

REMARKS

In view of the following remarks, reconsideration and further examination are respectfully requested.

Below is the status of the claims in this application:

1. Claim(s) pending: 28-53.
2. Claim(s) canceled: 1-27.
3. Claim(s) added: None.
4. Claims withdrawn from consideration but not canceled: None.

The drawings have been objected to because Figure 3 shows an absorbance spectra with absorbance units greater than 1, whereas, according to the Office Action, values above an absorbance unit of 1 is considered to be invalid based on the Beer-Lambert Law.

Claims 28, 29, 31-37, and 41-53 have been rejected under §102(b) as being anticipated by non-patent literature reference Janatsch et al., wherein the Office Action alleges that, with regard to independent claim 28, Janatsch teaches a method for screening biological samples for the presence of the metabolic syndrome in the sample donors, comprising irradiating the biological sample by radiation, capturing the radiation which has interacted with the biological sample, evaluating the captured radiation for spectral characteristics, and classifying the sample according to the presence of the metabolic syndrome based on the sample's spectral characteristics. Dependent claims are rejected on similar grounds based on additional alleged teachings from Janatsch.

Claims 30 and 38-40 have been rejected under §103(a) as being unpatentable over Janatsch in view of Mueller-Dethlefs (English language equivalent at US 6,868,285). The Office Action states that Janatsch fails to teach that the radiation is visible or near infrared radiation in the wavelength range of 0.6 to 1.5 micrometers, and the type of interaction is Raman scattering, but that Mueller-Dethlefs teaches this feature and thus it would have been obvious to modify Janatsch with Mueller-Dethlefs because according to the latter this would allow for continuous instead of a merely discreet monitoring of the values of the blood analysis.

In view of the following remarks, Applicant respectfully traverses each of the objections and rejections set forth in the Office Action, and requests that they be withdrawn.

Drawings – Figure 3 Absorbance Units

Absorbance is defined as the negative logarithm (to the basis of 10) of the ratio between transmitted intensity to incident intensity. As such, the absorbance can exhibit values anywhere between 0 and positive-infinity. The units given in Fig. 3 are used as a measure of absorbance and are given in absorbance units. The scale on Fig. 3 thus is correct in adopting values exceeding one absorbance unit, and as such no corrected drawing is required. Applicant respectfully requests the Examiner to withdraw the objection in this regard.

Anticipation by Janatsch NPL

As is set forth in the second paragraph under “Background” in the present application (paragraph [0004] of the publication US 2005/0158867), the metabolic syndrome is a cluster of risk factors which – next to clinical chemical parameters such as triglycerides or cholesterol – includes clinical findings such as hypertension and being overweight. The latter two risk factors cannot be measured by clinical analysis of blood. The analysis of chemical compounds alone is not appropriate to link the spectrum to a particular disease state.

While Janatsch describes the quantitative analysis of constituents in plasma by means of FT-IR spectroscopy, Applicant unexpectedly found that not only the level of lipid concentration but also these additional risk factors (hypertension, weight) are represented in the spectrum as is outlined in the patent application. It is this additional information which is important to enable the classification of metabolic syndrome spectra versus spectra originating from healthy volunteer's samples. It is thus surprising to find that risk factors such as high blood pressure or being overweight, which are usually not found in the clinical chemical analysis of blood, are reflected in the IR spectrum of serum, plasma or blood which in turn can be used for classification and thus for diagnosis of the metabolic syndrome. There is absolutely no link between the article of Janatsch and the metabolic syndrome. Indeed, nowhere in Janatsch is there any mention of the metabolic syndrome.

Because Claim 28 and all the claims dependent thereon recite a method for screening for the presence of metabolic syndrome, including the step of classifying the biological sample according to the presence of the metabolic syndrome based on the biological sample's spectral characteristics, and because Janatsch only teaches methods of quantitative analysis unrelated to the clinical findings inherently represented in the spectral characteristics of Claim 28, Janatsch

fails to disclose each and every element of these method claims, in particular that there even are spectral characteristics indicative of the presence of the metabolic syndrome.

Similarly, because Claim 41 and all the claims dependent thereon recite a system for screening for the presence of metabolic syndrome, including a classification unit for classifying the sample according to the presence of the metabolic syndrome based on the spectral characteristics, and because Janatsch only teaches systems relating to quantitative analysis unrelated to clinical findings inherently represented in the spectral characteristics of claim 41, Janatsch fails to disclose each and every element of these system claims, in particular that there even are spectral characteristics indicative of the presence of the metabolic syndrome that can be used to classify a sample by a classification unit as recited.

In view of the foregoing, Janatsch fails to disclose each and every element of the claims rejected on that basis, and thus cannot anticipate the claims as has been alleged in the Office Action. As a result, Applicant respectfully requests that the anticipation rejections be withdrawn.

Obviousness – Janatsch NPL in view of Mueller-Dethlefs

Because Janatsch does not teach each and every element of the independent claims rejected under §102(b) for the reasons stated above, then the Office Action fails to establish a prima facie case of obviousness of Claims 30 and 38-40 on the basis of Janatsch in view of Mueller-Dethlefs. The references cited in support of the obviousness rejections fail to disclose each and every element of the claims rejected on that basis. Thus, Applicant traverses the obviousness rejections and respectfully requests that they be withdrawn.

Mueller-Dethlefs describes the non-invasive quantification of glucose by means of Raman-Spectroscopy. Again, this method provides a means to quantify a particular parameter. Given the disclosure about the metabolic syndrome provided in the specification of the current application (paragraph [0004] of US 2005/0158867), a simple measure of clinical chemical parameters is not sufficient for a diagnosis of the metabolic syndrome. It was surprising that Applicant found that the analysis of serum by means of IR spectroscopy reflects the changes related to risk factors such as being overweight and hypertension in contrast to classical clinical chemical analysis. Surprisingly, it was thus further found that biomedical vibrational spectroscopy allows for the distinction between metabolic syndrome and a healthy state – well in excess of the simple quantification of blood analytes.

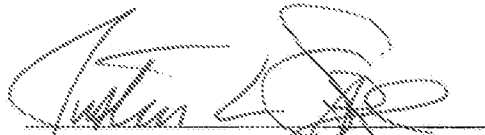
In view of the foregoing, the Office Action fails to set forth a prima facie case of obviousness and the rejections on this basis should be withdrawn.

Conclusion

In view of the above remarks, it is submitted that the present application is now in condition for immediate allowance, and the Examiner is requested to pass the case to issue. If the Examiner should have any comments or suggestions to help speed the prosecution of this application, the Examiner is requested to contact the Applicant's undersigned representative by telephone.

Respectfully submitted,

Date: September 17, 2008



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